

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-11, 13-15, and 17-20 were pending in this application when last examined.

Claims 1-6 have been examined on the merits, and claims 1, 2, 4, and 6 stand rejected.

Claims 3 and 5 are objected to.

Claims 7-11, 13-15, and 17-20 are withdrawn from consideration as non-elected subject matter.

The present amendment cancels claims 1-11, 13-15, and 17-20 without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

The present amendment adds new claims 21-38.

Claims 21-38 are now pending in this application.

Support for the nucleotide sequences of new claim 21 can be found in original claims 3 and 5 and in the Specification, for example, at page 4, lines 15-17, in Figure 1 (i.e., the nucleotide sequence of SEQ ID NO: 19), and in Figure 3 (i.e., amino acid sequence of SEQ ID NO: 20).

Support for the vectors, host cells, and methods of producing a protein having hydroxynitrile lyase activity of new claims 22-25 and 35 can be found in original claims 12 and in the Specification, for example, at page 6, lines 3-13, and Examples 6-9 on pages 18-20.

Support for the proteins and recombinant proteins having hydroxynitrile lyase activity of new claims 26-33 can be found in original claims 7-11 and 13-15 and in the Specification, for example, at page 6, lines 14-24, in Figures 3 and 5, and in Examples 6-10 on pages 18-22.

Support for the nucleotide sequence of the fusion protein and the fusion protein of new claims 34 and 35 can be found in original claim 12 and in the Specification, for example, at page 6, lines 3-13, and Example 10 on page 22, line 12 to page 24, line 3, in Figure 4 (i.e., SEQ ID NO: 21) and in Figure 5 (i.e., SEQ ID NO: 22).

Support for the method for producing (R)- or (S)-cyanohydrins of new claims 37 and 38 can be found in original claim 17 and in the Specification, for example, at Example 11 on page 24. Therefore, no new matter has been added by this amendment.

II RESTRICTION/ELECTION

In item 2 on page 2 it is indicated that claims 1-6 and SEQ ID NO: 10 are under consideration in view of the election dated December 12, 2003. However, please note that SEQ ID NO: 19 is the elected species. See page 6, line 6 of Applicants' election.

New claims 21-25 and 36-38 are directed to nucleotide sequences, host cells, vectors, methods of expressing, producing, and using the protein encoded by elected nucleotide sequence of SEQ ID NO: 19.

New claims 26-33 are directed to the protein and recombinant protein having hydroxynitrile lyase activity (i.e., SEQ ID NO: 20) encoded by the nucleotide sequence of elected SEQ ID NO: 19.

New claims 34 and 35 are directed to the nucleotide sequence encoding the fusion protein which contains the elected SEQ ID NO: 19.

Applicants respectfully request that the new claims directed to the proteins encoded by elected SEQ ID NO: 19 and the methods of expressing, producing, and using said proteins be rejoined and examined together with the claims directed to nucleotide sequence of elected SEQ ID NO: 19.

III. OBJECTIONS TO THE CLAIMS

Claims 3 and 5 are objected to for reciting non-elected subject matter. See page 1, items 3 and 5 and page 3, item 2 of the Office Action.

Claims have been cancelled and replaced by new claims 21-38 which are directed to the elected nucleotide sequence of SEQ ID NO: 19 as suggested by the Examiner, thereby obviating this objection.

IV. REJECTIONS UNDER 35 U.S.C. §§ 101 AND 112, UTILITY AND ENABLEMENT

Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. § 101 on the basis that the claimed invention allegedly lacks utility. Consequently, these same claims are also rejected under 35 U.S.C. § 112, first paragraph, as the Specification allegedly lacks an enabling disclosure for how to use the claimed invention. See pages 2-3, items 5, 6, and 8 of the Office Action.

These grounds of rejection are deemed to be overcome by cancellation of claims 1, 2, 4 and 6.

These rejections are also respectfully traversed as applied to the new claims in view of the following remarks.

The Specification discloses both a credible "well-established utility" and a credible "asserted utility" for the claimed nucleotide sequence (SEQ ID NO: 19) encoding a protein (SEQ ID NO: 20) having hydroxynitrile lyase of activity, and expression vectors and host cells thereto.

To satisfy the utility requirement under 35 U.S.C. § 101, the claims and the Specification must disclose either a credible "well-established utility" or a credible "asserted utility" for the claimed invention. M.P.E.P. § 2107.02.

A "well established utility" is a specific, substantial, and credible utility that must be immediately apparent to one skilled in the art based on the characteristics of the invention (e.g., properties or applications of a product or process). M.P.E.P. § 2107; *Guidelines for Examination of Applications for Compliance With the Utility Requirement*, 66 Fed. Reg. 1097, 1098 (Jan. 5, 2001). In other words, it must be well known, immediately apparent and implied by the specification based on the disclosure of the properties of the claimed invention, either alone or taken with knowledge of one skilled in the art.

A "specific asserted utility" is an explicit statement of "why the applicant believes that the invention is useful." M.P.E.P. § 2107.02. Such statements will usually explain the purpose of how the invention may be used. *Ibid.* A "substantial utility" defines a real world use. *Ibid.* Along these lines, only one credible assertion of specific and substantial utility for the claimed invention is necessary to satisfy the utility requirement. M.P.E.P. § 2107. Moreover, the threshold of utility is not high. See *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (Emphasis

added). Thus, if the asserted specific and substantial utility is considered credible by one skilled in the art, a rejection based on lack of utility is inappropriate. M.P.E.P. § 2107.

In the instant case, the Specification satisfies the requirements for a "credible asserted utilities." Applicants have discovered a novel *HNL5* gene nucleotide sequence (SEQ ID NO: 19) encoding a protein (SEQ ID NO: 20), as well as recombinant and fusion proteins thereof. Examples 13 and 14 (on pages 27-30) clearly demonstrate that the claimed the proteins encoded by elected SEQ ID NO: 19 are capable of producing cyanohydrins. As discussed at page 1, lines 20-34, of the instant Specification and in column 1, lines 6-20 of Hasslacher et al., U.S. Patent No. 6,046,042 (cited in the IDS) hydroxynitril lyases are important in the industrial production of the chiral compounds, such as cyanohydrins. Furthermore, as disclosed at page 1, lines 20-26, cyanohydrins are important in the synthesis of α -hydroxy acids, α -hydroxyketones, and β -aminoalcohols which are useful for producing biologically active pharmaceutical substances, such as vitamins or pyrethroid compounds. The Specification, at page 4, lines 10-35, also discloses significant sequence identity between the claimed *HNL5* gene and those in the prior art (e.g., *HNL5* and *MDL1*) encoding known hydroxynitrile lyases. Thus, in view of such a disclosure, the claimed invention is useful in the pharmaceutical industry for producing cyanohydrins. Clearly, this asserted utility of the claimed invention would have been recognized as credible by those skilled in the art at the time of the claimed invention.

It is well established that such asserted utilities are *presumed true*. M.P.E.P. § 2107.01 and *In re Brana*, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (Emphasis added). To overcome the presumptive truth of the asserted specific utilities set forth in the specification, the Office must show by a *preponderance of evidence* that it is *more likely than not* that the asserted specific utility would be considered false by a person of ordinary skill. M.P.E.P. § 2107.01 and *In re Corkill*, 226 U.S.P.Q. 1005, 1008 (Fed. Cir. 1985) (Emphasis added).

Applicants submit that the Office has failed to overcome this presumption because no evidence or arguments have been presented that specifically contradict the asserted utility set forth in the Specification and discussed above. In other words, the Office has not shown by a preponderance of evidence that it is more likely than not that the asserted specific utilities would

be considered false by a person of ordinary skill in the art. Instead, the Examiner relies on four basic arguments to support his rejection for lack of utility and the corresponding lack of enablement rejection.

Therefore, the rejections of claims 1, 2, 4, and 6 under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph are untenable, and not applicable to the newly added claims.

V. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, LACK OF ENABLEMENT

Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification is not enabling for any nucleotide sequence that is at least 80% identical to SEQ ID NO:19 and encodes a hydroxynitrile lyase. See pages 3-5, item 9 of the Office Action.

The present amendment cancelling this claim is deemed to overcome this rejection.

VI. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification lacks written description support for the genus of genes containing any DNA encoding for any hydroxynitrile lyase. See page 5, item 10 of the Office Action.

The present amendment cancelling these claims is deemed to overcome this rejection.

VII. REJECTIONS UNDER 35 U.S.C. § 102

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Hu et al., Accession U51562 a copy of which is enclosed. See pages 5-6, item 12 of the Office Action.

The present amendment cancelling these claims is deemed to overcome this rejection.

Furthermore, it has been shown in the Examples that proteins derived from genes with SEQ ID NO: 19 have improved properties such as higher stability and need of less amount to achieve high enantiomeric purity.

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CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance and early notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below if he has any suggestions to expedite allowance of the present application.

Respectfully submitted,

Helmut SCHWAB et al.

By: 
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/JFW/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
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